IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

STRECK, Inc., a Nebraska corporation, Plaintiff, v. RESEARCH & DIAGNOSTIC SYSTEMS, Inc., a Minnesota corporation, and TECHNE, Corporation, a Minnesota corporation, Defendants.	)	8:06CV458 MEMORANDUM AND ORDER

This matter is before the court on defendants Research & Diagnostic Systems, Inc., and Techne Corporation's (collectively, "R&D's") renewed motion for judgment as a matter of law and motion for a new trial, Filing No. 326. This is an action for patent infringement that was tried to a jury from October 19, 2009, to October 28, 2009. Streck, Inc. ("Streck") alleged that R&D sold integrated hematology control products ("the accused products")[1] that violated Streck's patent rights under three of its patents.[2] R&D asserted the defenses of invalidity and priority of invention and counterclaimed for a declaratory judgment of noninfringement and invalidity. The court ruled on several issues as a matter of law and submitted the prior invention issue to the jury for resolution. The jury found in favor of Streck. *See* Filing No. 315, Special Interrogatories (Jury Verdict). R&D challenges the jury's finding as well as the court's findings, as a matter of law, that Streck's patents

[1]Specifically, the "CBC-XE," the "CBC-4K Plus Retics," and the "CBC-5D Plus Retics" integrated hematology control products. Filing No. 1, Complaint

[2]Specifically, United States Patent No. 6,200,500, ("the '500 patent"); United States Patent No. 6,221,668 ("the '668 patent"), and United States Patent No. 6,399,388 ("the '388 patent") (collectively, "the Streck patents"). Filing No. 1, Complaint, Exhibits ("Exs.") A - C.

properly enabled the invention and that R&D's parent corporation, defendant Techne, is liable for infringement.[3]

I. FACTS

By way of background, this action involves hematology control products. These products are used to test automated hematology instruments that measure the components in human blood for medical and diagnostic purposes. There are four major manufacturers of hematology instruments (Coulter, Abbott, Bayer, and Sysmex) and each makes instruments that count the components—red cells, the five-part white cell differentials,[4] platelets and reticulocytes in human blood. The purpose of a control is to monitor the performance of a machine. Laboratories, hospitals, clinics and doctor's offices use controls to test the accuracy and reliability of the hematology instruments.

Both Streck and R&D manufacture and sell hematology control products. The products at issue in this case are integrated reticulocyte controls. An integrated reticulocyte control is a control for an instrument capable of analyzing the components of human blood—red cells, five subpopulations of white cells (lymphocytes, monocytes, neutrophils, eosinophils, and basophils), platelets, and reticulocytes—with one sample. *Id.* at 23.

[3]The court's consideration of this motion was held in abeyance pending the submission and argument on Streck's appeal of the United States Patent Office ("USPTO") Board of Patent Appeals and Interferences ("Board") decision on priority. *See Streck v. Research and Diagnostic Systems, Inc.*, No. 8:09CV410 (D. Neb.). Additional facts can be found in the court's order reversing the Board's decision. See Findings of Fact Memorandum Opinion in case no. 8:09CV410 entered on this date.

[4]The five different types of white cells that are normally found in human blood are lymphocytes, monocytes, neutrophils, eosinophils, and basophils.

The evidence adduced at trial establishes the following facts. *See* Filing Nos. 330, Trial Transcript (Vol. I); 331, Trial Transcript (Vol. II); 332, Trial Transcript (Vol. III); 333, Trial Transcript (Vol. IV); 334, Trial Transcript (Vol. V); 335, Transcript (Vol. VI); 336, Trial Transcript (Vol. VII) and 337, Trial Transcript (Vol. VIII) ("T. Tr."). Dr. Wayne Ryan, the majority owner and Chief Executive Officer of Streck, and John Scholl, Streck's Research and Development Manager, are the named inventors of the patents at issue, all of which have been assigned to Streck. Filing No. 330, T. Tr. (Vol. I) at 18, 37. Dr. Ryan filed his application for the '500 patent related to integrated hematology control technology on August 20, 1999, and the '500 patent issued on March 13, 2001. Filing No. 1, Complaint, Ex. A. Dr. Alan Johnson is a senior scientist in R&D Systems' Hematology Division. Filing No. 334, T. Tr. (Vol V) at 940-41. He filed a patent application for an integrated hematology control on October 18, 1999 (the "'991 application"). T. Ex. 1224.

Dr. Ryan testified that sometime in 1993, he learned that Abbott Laboratories was developing a pioneering hematology instrument that would measure reticulocytes and the five different white blood cells simultaneously. Filing No. 331, T. Tr. (Vol. II) at 404; *see also id. at* 306-07 (testimony of John Scholl); Filing No. 330, T. Tr. (Vol. I) at 125-127, 164 (testimony of Patrick Tran); Filing No. 332, T. Tr. (Vol. III) at 573-74, 625-26 (testimony of James Janik); Trial Exhibit ("T. Ex.") 130 at 5. Previously, instruments had measured these two components separately, requiring at least two preparations of composition to be tested. Filing No. 331, T. Tr. (Vol. II) at 306 (testimony of Scholl). In late 1993, Dr. Ryan directed his laboratory assistant, Patrick Tran, to conduct experiments by adding reticulocytes to various control products with the objective of determining if the reticulocytes would interfere with the white cells or vice-versa. *Id.* at 306-07. Tran prepared several compositions and

tested them on four hematology instruments (the Bayer H*3, Sysmex R1000, Abbott Cell-Dyn 3000, and Coulter S+IV). Filing No. 330, T. Tr. (Vol. I) at 125-26. The result of those experiments was that it was feasible to add reticulocytes to a complete control "without interference from white blood cells." *Id.* at 139; *see also* Filing No. 331, T. Tr. (Vol. II) at 306-15 (testimony of Scholl); 392-95, 397-99 (testimony of Dr. Wayne Ryan); T. Exs. 126 & 130. Tran discussed the results of the experiments with Dr. Ryan and John Scholl and provided them his observations and data. Filing No. 330, T. Tr. (Vol. I) at 140; Filing No. 331, T. Tr. (Vol. II) at 397-98 (testimony of Dr. Ryan). Tran recorded the observations in a laboratory notebook, and preserved the related data and scattergrams in a project folder. Filing No. 330, T. Tr. (Vol. I) at 121, 127-28 (testimony of Tran). Although, at that time, none of the instruments could perform simultaneous measurements of both reticulocytes and white blood cells, Dr. Ryan was able to determine that there was no excessive interference between the reticulocyte component and the white blood cell component by comparing results from the different instruments. Filing No. 331, T. Tr. (Vol. II) at 393-94, 397-98 (testimony of Wayne Ryan).

Dr. Elkin Simson, an expert who testified on behalf of R&D, stated that Dr. Ryan's 1993 experiment was a complete conception. Filing No. 336, T. Tr. (Vol. VII) at 1418-19. Dr. Johnson testified he had conceived the invention in 1995. Filing No. 334, T. Tr. (Vol. V) at 1059-60; *see also* Filing No. 336, T. Tr. (Vol. VII) at 1418-19 (testimony of Dr. Simson). Accordingly, it is not disputed that Dr. Wayne Ryan was the first to conceive the invention.

Further experimentation such as stability studies were not pursued at that time at Streck because "it was just a fact gathering mission in a way, and the analyzers that we

ran it on would not be the same analyzers down the road once they came out with it, and we were primarily interested in seeing if there is any interference." Filing No. 330, T. Tr. (Vol. I) at 143 (testimony of Tran). Between 1993 and 1997, Streck did not have "one instrument that could take one aspiration of a blood sample and give you all the results. That analyzer did not exist." *Id.* at 164. Instrument manufacturers began launching integrated hematology instruments in 1996. Filing No. 330, T. Tr. (Vol. I) at 34-35 (testimony of Constance Ryan). In 1996, Coulter developed, and Streck acquired, a module on which to run reticulocytes together with a white blood cell differential. Filing No. 331, T. Tr. (Vol. II) at 315 (testimony of Tran). Abbott launched the Cell-Dyn 4000 for sale to the public in 1997. *Id*. at 352. Hematology machines cost $40,000 to $150,000. Filing No. 330, T. Tr.(Vol. I) at 14 (testimony of Constance Ryan).

Beginning in early 1997, Dr. Ryan and John Scholl at Streck worked on projects aimed at developing an integrated control with reticulocytes. Filing No. 331, T. Tr. (Vol. II) at 232 (Tran testimony). A control composition that “worked” would be one that lacked interference, with cells properly positioned, and was stable over time. Filing No. 331, T. Tr. (Vol. II) at 211 (testimony of Tran); Filing No. 334, T. Tr. (Vol. IV) at 754 (testimony of Dr. Langley). Both Janik and Dr. Langley testified that in order to determine if a control “worked,” one would have to look at a scattergram. Filing No. 334, T. Tr. (Vol. IV) at 758-59.

A scattergram is a visual representation of the positioning of cell populations by type, according to an instrument's mathematical algorithms (or software). Filing No. 330, T. Tr. (Vol. I) at 130 (testimony of Tran). The positioning is generally determined by cell size, shape, and the amount of light it scatters. *Id.* (Tran); *see also* Filing No. 334 , T. Tr.

(Vol. IV) at 758-60 (testimony of Dr. Robert Langley) (stating that a scattergram is a graphical representation of the different cell types, "a pictorial representation of what the software or the algorithms have done," showing that the cell population is "in the areas where the computer algorithm of the instrument expects them to be"). Based on the cells' relative positions, the scattergram displays the instrument's classification of the populations of the various types of cells. Filing No. 333, T. Tr. (Vol. IV) at 758-60 (testimony of Dr. Langley); Filing No. 332, T. Tr. (Vol. III) at 584-86 (testimony of James Janik).

The analysis of a scattergram will show if there is overlapping between the different cell types, known as interference. Filing No. 332, T. Tr. (Vol. III) at 588-93, 602. Dr. Ryan and Patrick Tran, as well as Streck expert witnesses James Janik and Dr. Robert Langley, all testified that scattergrams are the only means for determining whether such interference is occurring or is likely to occur in a control composition that is being developed. Filing No. 331, T. Tr. (Vol. II) at 404-05 (testimony of Dr. Ryan); Filing No. 330, T. Tr. (Vol. I) at 130 (Tran); Filing No. 332, T. Tr. (Vol. III) at 588-593 (Janik); Filing No. 333, T. Tr. (Vol. IV) at 758-60 (Dr. Langley). R&D's expert witness, Dr. Elkin Simson, conceded that scattergrams are necessary in designing a control. Filing No. 336, T. Tr. (Vol. VII) at 1419, 1426.

Streck produced voluminous and meticulous records of experiments, including laboratory notebook entries, lab notes, data, and scattergrams from testing the control substances on various hematology instruments, that show that Dr. Ryan and his staff developed integrated reticulocyte controls that worked for each of several machines beginning with Streck project 97034 in February 1997. *See, e.g.,* T. Ex. 648. Streck's expert witness, Dr. Langley, testified that the numerical results of the experiments demonstrated that each control had sufficient stability. Filing No. 333, T. Tr. (Vol. IV) at

734-41, 750. Dr. Langley and Mr. Janik testified that they examined the scattergrams for the projects and that the cell populations were properly positioned in the scattergram without substantial interference. *Id.* (Langley); Filing No. 332, T. Tr. (Vol. III) at 622-23, 627-30 (Janik). R&D's expert, Dr. Simson, also acknowledged that Streck's experiments in 1997 amounted to successful reductions to practice. Filing No. 336, T. Tr. (Vol. VII) at 1386. The evidence shows that Streck continued to work on and refine the integrated reticulocyte controls from shortly after it first acquired a machine on which to test the integrated controls in 1996 until Dr. Ryan filed the patent application in August of 1999. See Tr. Exs. 144 & 147 (showing experiments on an integrated control for the Sysmex XE 2100); Filing No. 331, T. Tr. (Vol. II) at 197-203 (testimony of Tran); T. Ex. 148 at 168-171; T. Ex. 151; Filing No. 331, T. Tr. (Vol. II) at 271-73 (showing experiments on an integrated control for use on an Abbott CD-4000); T. Ex. 137 at 52-55; T. Ex. 157; Filing No. 331, T. Tr. (Vol. II) at 204-10 (showing experiments on an integrated control for use on a Bayer Advia 120 instrument).

Streck announced it was preparing to market an integrated reticulocyte control at a trade show in July of 1999. Filing No. 330, T. Tr. (Vol. I) at 45-46. It filed its patent application in August 1999 and commercially released its first integrated reticulocyte control (Stak-Chex Plus Retics®) shortly thereafter, in December of 1999. T. Ex. 190; Filing No. 331, T. Tr. (Vol. II) at 326-28 (testimony of Scholl). Within the next year, Streck introduced integrated reticulocyte controls for a number of other instruments. Tr. Exs. 194-195; Filing No. 331, T. Tr. (Vol. II) at 328-29 (Scholl).

The evidence also showed that Dr. Johnson had similarly experimented on integrated reticulocyte controls at R&D beginning in mid-1996. *See* T. Exs. 1039, 1061,

and 1057. On July 17, 1996, Dr. Johnson made two samples containing a reticulocyte component and a white blood cell component (Johnson Controls 1 and 2), and his research assistant, Paul Nansen, ran those samples on an Abbott Cell-Dyn 4000 instrument. *See* T. Ex. 1039. In the six-page exhibit that is the record of the experiment, only the notation "CBC-3K U076 + RETIC 2 960507" at the top of the first page of the exhibit indicates the formulation of components in the sample. *Id.* at 1. The exhibit contains graphs, two sheets of raw data and a single scattergram for the experiment.[5] *Id.* at 3-5; *see also* Filing No. 334, T. Tr. (Vol. V) at 1082-83, 1087 (testimony of Dr. Johnson); 1170 -71(testimony of Nansen). There are no other scattergrams that would show whether there were shifts in cell population over time. Filing No.334, T. Tr. (Vol. V) at 1083-1084 (testimony of Dr. Johnson).

Two more samples (Johnson Controls 3 & 4) were run on a STKS instrument from July through October 3, 1996. T. Ex. 1061. The only data that exists for the testing of Johnson Controls 3 & 4 are three pages of data attached to a 1998 memorandum from Alan Johnson to R&D's upper management summarizing work done on "5D Controls with Reticulocytes." *Id.* at 4-6; Filing No. 334, T. Tr. (Vol. V) at 1064-68 (Dr. Johnson testimony). None of the original data that would have been generated by the instrument during this experiment has been produced. Filing No. 334, T. Tr. (Vol. V) at 1068-69 (Johnson testimony acknowledging that the data provided in the exhibit was from a spread sheet he prepared). There are no scattergrams for this experiment, nor is there any

[5]That exhibit contains results of tests run on other samples that R&D does not contend are reductions to practice, labeled "CDC-3K LOT U096 + RETIC2 960619." T. Ex. 1039 at 2, 6, Filing No. 334, T. Tr. (Vol. V) at 982 (testimony of Dr. Johnson). Those results demonstrate a lack of stability. Filing No. 334, T. Tr. (Vol. V) at 982-83. Page 6 of that exhibit is a scattergram that is unrelated to Johnson Controls 1 & 2. *Id.* at 1082-83.

evidence that Dr. Johnson reviewed any scattergrams for Johnson Controls 3 & 4. Tr. Ex. 1061; Filing No. 334, T. Tr. (Vol. V) at 1068 (Dr. Johnson testimony).

The only indication of the formulation, components, or relative percentages of components that comprise Johnson Controls 3 & 4 is the title "5D 3PL + RET" on the exhibit. Tr. Ex. 1061 at 5-6. Dr. Johnson's research assistant, Paul Nansen, testified that Dr. Johnson made up the vials and would have had to tell Nansen what the components were in order for Nansen to have made up the graphs and tables, but Nansen could remember no specifics. Filing No. 335, T. Tr. (Vol. VI) at 1173. Dr. Johnson's testimony regarding the components of the experimental compositions was vague and contradictory. *See, e.g.*, Filing No. 334, T. Tr. (Vol. V) at 971, 979-80, 1069-72. He stated that he used commercial compositions and knew at the time what was in them but was not able to state with any specificity the percentages of components or the buffers used. *Id.* at 1069-72. There is no evidence with respect to the ingredients, components, buffers or fixatives that comprised the prototypes "5D3PL" or "5D3PN" or R&D's commercial formulations at the time the tests on Johnson Controls 1-4 were performed. *Id.* at 1070. Diluents also affect how a control works. Filing No. 332, T. Tr. (Vol. III) at 606 (testimony of Janik).

Neither Mr. Nansen nor Dr. Johnson's superior, Dr. Thomas Detwiler, could recall the dates or specifics of any conversations in which they would have discussed the results of the integrated reticulocyte control experiments with Dr. Johnson. Filing No. 335, T. Tr. (Vol. VI) at 1173 (Nansen); 1069-70 (Detwiler). Dr. Detwiler had no recollection of reviewing the results of these experiments at the time they were preformed. *Id.* at 1225-26.

Streck's expert, James Janik, reviewed the evidence in support of Johnson Controls 1-4 and stated that the evidence it was not sufficient to enable him to determine whether

the experimental samples worked for their intended purposes. Filing No. 336, T. Tr. (Vol. VII) at 1460-67 (testimony of Janik). Dr. Johnson later conducted experiments with another composition (Johnson Control 5). Filing No. 334, T. Tr. (Vol. V) at 1091-93. Dr. Johnson testified that he did not know whether or not the Johnson Control 5 composition worked until early September of 1997. *Id.* at 1092-93; *see also* T. Ex. 1057. Dr. Johnson wrote in his quarterly report to his superior: "If the retic targets [in Johnson Control 5] were lowered slightly it appears that this combined control could be dated for about 2 months. This project appears to have disappeared from the priority list and there are no plans at this time to build additional lots." Tr. Ex. 1057 at RDS-13680. Dr. Johnson also indicated that samples tested on the Cell-Dyn 4000 "show[ed] unacceptable reticulocyte stability." T. Ex. 1052 at RDS-15706; *see also* T. Ex. 1053 at 6; Filing No. 334, T. Tr. (Vol. V) at 1087-89 (Johnson testimony). Experiments performed in 1999 and 2000 show that R&D continued to have problems with interference that related to buffers used in an integrated control composition it prepared for the College of American Pathologists. Filing No. 334, T. Tr. (Vol. V) at 1071 (Dr. Johnson testimony).

The evidence also shows that R&D did not consider the 1996 and 1997 experiments to have been successful—after the testing on Johnson Control 5 in late 1997, R&D did not attempt to make another sample of integrated reticulocyte control until 2003. Filing No. 334, T. Tr. (Vol. V) at 1100 (testimony of Dr. Johnson). There is no evidence that R&D later relied on any of the results from Dr. Johnson's 1996 and 1997 experiments. *Id.* at 1093-97; *see also* T. Ex. 93; T. Ex. 541 at RDS-021583 (stating that "[o]ther current reticulocyte analogs interfere with the differential on all analyzers and are not feasible. We

are in the process of feasibility testing of a variety of ideas to obtain and stabilize human reticulocytes in order to move towards the CBC plus retic products.").

Reticulocytes are "anucleate immature red blood cells containing some ribonucleic acid [RNA]." See Filing No. 135, Memorandum Opinion (Claim Construction) at 14-15. Streck's integrated control compositions contain human red blood cells with encapsulated RNA as a reticulocyte analog. Filing No. 332, T. Tr. (Vol. III) at 452-54 (testimony of Dr. Ryan); Filing No. 333, T. Tr. (Vol. IV) at 676 (Janik testimony). R&D's infringing products use porcine red blood cells as a reticulocyte analog. Filing No. 334, T. Tr. (Vol. V) at 969, 980 (testimony of Dr. Johnson). Dr. Ryan testified that a person of ordinary skill in the art would be able to create a control composition using animal cells as analogs from the information contained in his patent, given the state of the science at the time. Filing No. 332, T. Tr. (Vol. III) at 406, 504-05, 508 (Dr. Ryan testimony). James Janik also testified that the patents disclose enough information that a person of ordinary skill in the art could make a control using a different analog, such as an animal analog. Filing No. 333, T. Tr. (Vol. IV) at 672. James Janik also testified that the technology of a reticulocyte analog was already known at the time Streck filed its patent application. *Id.* at 671-72, 684. Dr. Ryan had developed a control composition using rabbit cells, but stopped using it for practical reasons associated with having to house too many rabbits. Filing No. 331, T. Tr. (Vol. II) at 385-86 (testimony of Dr. Ryan). Dr. Ryan testified that it was not realistic and impractical to use animal reticulocytes in an integrated control. Filing No. 332, T. Tr. (Vol. III) at 460.

The evidence also shows that R&D is a wholly-owned subsidiary of Techne, a holding company with no employees. Filing No. 334 , T. Tr. (Vol. V) at 914 (testimony of

Thomas Oland). The two companies occupy the same physical location and file consolidated financial statements. *Id.* The individuals in charge of operations at R&D are also officers of Techne. *Id.* at 883 (Oland testimony). Mr. Oland is the Chairman of the Board, President, CEO and Treasurer of Techne and is also the President of R&D. *Id.* Mr. Marcel Veronneau is the Vice President of Hematology Operations at both R&D and Techne. *Id.* at 898-900. Veronneau made the decision to launch the products that are the subject of this infringement action, and warned Techne management that: "the release of this product (our first 5 part differential control with addition of reticulocytes) may also trigger a legal action by Streck." T. Ex. 24 at RDS-022415.

At the close of evidence, the court sustained Streck's motion for judgment as a matter of law on the issue of joint and several liability between R&D and Techne, finding there was no difference between the two corporations with respect to the patent infringement liability. The court also found in favor of Streck on the enablement issue, stating:

> The defendants' enablement defense rests on a semantic construction of the '500 patent and in the '500 patent there are claims about reticulocytes, naturally occurring reticulocytes or analogs thereof. Everybody agrees that if you fix human reticulocytes that you could do the control that Dr. Ryan described in his '500 patent. Everybody agrees that if you use encapsulated reticulocytes that you could use Dr. Ryan's invention to describe that. The question is whether or not you could use naturally occurring reticulocytes specifically in pigs. I have two problems with that. One is a pig reticulocyte is not a human reticulocyte, so it's obviously an analog of a human reticulocyte. That's the first thing. The second thing is Dr. Ryan testified that he had used rabbit reticulocytes earlier and decided that he didn't like using them because it was too hard to get them and it was an economic decision with respect to using rabbit reticulocytes, but that he had already reduced that use to practice and had a control, a single standing control for rabbit reticulocytes. And no one has testified that Dr. Ryan's formulation would make any difference whether it was used for human reticulocytes, naturally occurring reticulocytes, or encapsulated reticulocytes, which incidentally are

> made from human blood cells. So if you take all of that and put it together it seems to me that the invention that Dr. Ryan described is enabled. And furthermore the testimony from R & D's own people is they understood that if they tried to put on the market their invention that it would be in violation of Dr. Ryan's patent.

Filing No. 336, T. Tr. (Vol. VII) at 1518-19.

The court overruled the parties' motions for judgment as a matter of law on the issues of who was the first to invent, damages and willfulness. *Id.* The court found that Dr. Ryan was the first to conceive, but submitted the issues of priority of invention, abandonment, suppression, and concealment to the jury for its determination. *Id.* at 1498-1520. The jury was instructed that R&D had to prove "by clear and convincing evidence (1) that before [Dr. Ryan] reduced his invention to practice, Dr. Alan Johnson reduced to practice a product or method that included all of the elements of [the relevant claims of the patents at issue] and (2) that Dr. Alan Johnson did not abandon, suppress, or conceal his invention before October 18, 1999." Filing No. 319, Final Jury Instructions, Instruction No. 20. Further, it was instructed that "[a]n invention requires both conception and reduction to practice. A claimed invention is reduced to practice when the inventor has shown and understands that it will work for its intended purpose or when it is fully described in a filed patent application." Filing No. 319, Final Jury Instruction No. 22.

II. DISCUSSION

A. Law

Under Rule 50 of the Federal Rules of Civil Procedure, "[i]f a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue, the court may . . . (A) resolve the issue against the party; and (B) grant a motion for judgment as a matter

of law against the party on a claim or defense that, under the controlling law, can be maintained or defeated only with a favorable finding on that issue." Fed. R. Civ. P. 50(a)(1). The district court can grant a posttrial motion for judgment as a matter of law only if there is "'a complete absence of probative facts to support the conclusion reached' so that no reasonable juror could have found for the nonmoving party.'" *Sheriff v. Midwest Health Partners, P.C.*, --- F.3d ----, 2010 WL 3385247, *3 (8th Cir. August 30, 2010) (quoting *Hathaway v. Runyon*, 132 F.3d 1214, 1220 (8th Cir.1997)). "The evidence must be viewed in the light most favorable to the nonmoving party while assuming as proven all facts [its] evidence tends to show, resolving all evidentiary conflicts in [its] favor, and according [it] all reasonable inferences." *Id.* A reasonable inference is one that may be drawn from the evidence without resort to speculation. *First Union Nat. Bank v. Benham,* 423 F.3d 855, 863 (8th Cir. 2005). "Judgment as a matter of law is appropriate '[w]hen the record contains no proof beyond speculation to support [a] verdict.'" *Id.* (quoting *Sip-Top, Inc. v. Ekco Group, Inc.*, 86 F.3d 827, 830 (8th Cir. 1996)). A new trial should only be granted when necessary to prevent a miscarriage of justice. *Maxfield v. Cintas Corp.*, 563 F.3d 691, 694 (8th Cir. 2009). This means that a new trial "should only be granted if the evidence weighs heavily against the verdict." *Id.*

A patent is entitled to a presumption of validity. *Apotex v. Merck & Co.*, 254 F.3d 1031, 1036 (Fed. Cir. 2001). The first inventor is the first party to reduce an invention to practice unless the other party can show that it was the first to conceive the invention and that it exercised reasonable diligence in later reducing that invention to practice. *Monsanto Co. v. Mycogen Plant Sci., Inc.,* 261 F.3d 1356, 1362 (Fed. Cir. 2001). The party

challenging a patent under § 102(g)(2) must prove facts supporting a determination of invalidity by clear and convincing evidence. *Apotex*, 254 F.3d at 1036.

Priority of invention, and its underlying issues of conception and reduction to practice, are "questions of law predicated on subsidiary factual findings." *Taskett v. Dentlinger*, 344 F.3d 1337, 1339 (Fed. Cir. 2003); *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1362 (Fed. Cir. 2004) (noting, with respect to a post-verdict motion for judgment as a matter of law on a mixed question of law and fact, that the jury's conclusion must be sustained unless the jury was not presented with substantial evidence to support any set of implicit findings sufficient under the law to arrive at its conclusion). Conception is the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Invitrogen Corp. v. Clontech Laboratories, Inc.*, 429 F.3d 1052, 1063 (Fed. Cir. 2005). "An idea is sufficiently definite and permanent for conception if it provides one skilled in the art with enough guidance to 'understand the invention,' that is, 'when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue.'" *Id.* (quoting *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir.1994). The inventor must be able to describe his invention with particularity, which requires both (1) the idea of the invention's structure and (2) possession of an operative method of making it. *Invitrogen Corp.*, 429 F.3d at 1063. Conception requires that the inventor appreciate that which he has invented. *Id.* (noting that the date of conception of a prior inventor's invention is the date the inventor first appreciated the fact of what he made).

An inventor's—or challenger's—testimony, standing alone, is insufficient to prove conception; some form of corroboration must be shown. *Price v. Symsek*, 988 F.2d 1187, 1194 (Fed. Cir. 1993). Corroboration may be in the form of testimony from other persons, drawings or models with adequate time identification, or any other documentation that fixes the time of invention. *Id.* at 1194-95. "An evaluation of all pertinent evidence must be made so that a sound determination of the credibility of the inventor's story may be reached." *Id.* at 1195.

A party asserting invalidity of patent based on prior invention bears the burden of demonstrating by clear and convincing evidence that its product constituted an actual reduction to practice of the invention claimed in challenged patents. *Z4 Technologies, Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1352 (Fed. Cir. 2007). "'In order to establish an actual reduction to practice, the inventor must prove that: (1) he constructed an embodiment or performed a process that met all the limitations . . . and (2) he determined that the invention would work for its intended purpose.'" *Id.* (*quoting Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998)). Testing is required to demonstrate reduction to practice in some instances because without such testing there cannot be sufficient certainty that the invention will work for its intended purpose. *Id.* The necessity and sufficiency of such testing are factual issues. *Id.* (stating that substantial evidence in the record that supports a finding that a purported invention did not work for its intended purpose will support a jury's verdict that patents are not invalid for anticipation). Importantly, "when testing is required to establish that the invention works for its intended purpose, the inventor must at the time appreciate that such testing is successful." *Manning v. Paradis*, 296 F.3d 1098, 1104 (Fed. Cir. 2002).

One who is second to conceive but first to actually reduce an invention to practice nonetheless loses priority of invention if he thereafter abandons, suppresses or conceals the invention. *Lutzker v. Plet*, 843 F.2d 1364, 1366 (Fed. Cir. 1988). Abandonment, suppression, and concealment may be established by proving that the inventor actively suppressed his invention from the public in order to prolong the period during which the invention is secret. *Paulik v. Rizkalla*, 760 F.2d 1270, 1273 (Fed. Cir. 1985) (en banc). Evidence that the inventor intended to wait to disclose his invention until his company was ready to manufacture it supports a finding of intentional suppression. *Young v. Dworkin*, 489 F.2d 1277, 1281-82 (C.C.P.A. 1974). Evidence that an inventor was spurred to disclose or apply for a patent by the activities of another inventor is an important factor in finding abandonment, suppression, or concealment because it suggests that, but for the efforts of the latter inventor, the former inventor would never have disclosed his invention to the public. *Id.*

The statutory basis for the enablement requirement is found in 35 U.S.C. § 112, ¶ 1, which provides in relevant part:

> The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112. For a patent to satisfy the enablement requirement, the specification must enable "those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation.'" *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365 (Fed. Cir.1997) (quoting *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir.1993)).

In determining whether undue experimentation is required to practice the claimed invention, the court considers: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance disclosed in the patent; (3) the presence or absence of working examples in the patent; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (6) the predictability of the art; and (7) the breadth of the claims. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). The court is required only to consider those factors that are relevant. *See, e.g.,* *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991). Although underlying factual inquiries must be made to determine whether a patent is enabled, enablement is ultimately a question of law. *Enzo Biochem, Inc. v. Calgene*, Inc., 188 F.3d 1362, 1369 (Fed. Cir. 1999).

If there is a "substantial and continuing relationship" shared between two companies, the corporate distinction between the two organizations can be disregarded. *See* *A. Stucki Co. v. Worthington Industries, Inc.*, 849 F.2d 593, 596 (Fed. Cir. 1988) (holding that a holding company's ability to control a subsidiary and stop alleged infringement required imputing liability on the parent); *see also* *Frank Music Corp. v. MGM, Inc.*, 886 F.2d 1545, 1553 (9th Cir. 1989) (holding that a parent was jointly liable for a subsidiary's copyright infringement where the two shared a "substantial and continuing relationship"). Another important factor is whether acts of a subsidiary may be attributed to the parent because of the "degree of control over, knowledge of, and benefit from the actions" of the subsidiary by the parent. *A.H. Robins v. Zoo-Techniques*, 204 U.S.P.Q. 387, 390 (E.D. Va. 1979) (discussing in the context of venue). The following factors are relevant to the determination that two corporations are "truly separate:" (1) overlapping directors and officers between the two companies, (2) payment of taxes and filing of

consolidated returns, (3) level of parental financing and control over the subsidiary, and (4) the authority (or lack thereof) over the day-to-day activities. *See* *Phoenix Canada Oil Co. Ltd. v. Texaco, Inc.*, 842 F.2d 1466, 1476-77 (3d Cir. 1988); *Burke v. Citigroup, Inc.*, 2006 WL 3483787, *3 (D. Neb. Nov. 29, 2006). Also, a parent can be held being liable for a subsidiary's activities under general agency theory. *Burke,* 2006 WL 3483787 at *6.

B. Analysis

The court finds that the evidence presented at trial in this case supports the jury's finding that R&D did not prove by clear and convincing evidence that Dr. Johnson was the first to invent an integrated reticulocyte control composition. Further, the court finds the evidence supports the court's finding as a matter of law that Streck's patents were adequately enabled. Also, the court finds no error in the finding that Techne Corporation is jointly liable for patent infringement.

The evidence shows that in order to work for their intended purpose, that is, to be useful to monitor the performance of a hematology instrument, a control must be sufficiently stable over time, and must not exhibit substantial interference between the components. Interference or lack thereof is shown by proper positioning on a scattergram.

The undisputed evidence establishes that Dr. Wayne Ryan was the first to conceive of the invention. The evidence shows that Dr. Ryan conceived the invention on November 15, 1993. From that date until mid-to-late 1996, Streck did not have a hematology instrument on which it could further test an integrated control. The evidence that there was no reason to develop a control for a machine that did not yet exist would support a jury's finding that a period of inactivity by Streck from 1993 to 1996 was excused. The jury could

have concluded that there was no need for Streck to commercially develop an integrated control with reticulocytes until there was a machine on which it could be used.

Once the machine was released, the evidence shows that Streck acquired the machine and worked diligently to reduce Dr. Ryan's conception to practice. Streck presented documented evidence of experiments that resulted in a control composition that worked for its intended purpose no later than May of 1997. All of Streck's projects are corroborated by voluminous contemporaneous data, including laboratory notebook entries, lab notes, data and scattergrams.

R&D attempted to show that it had successfully reduced the invention to practice before Streck's first reduction to practice. Although R&D showed that it had performed some experiments in mid-1996, it did not present clear and convincing evidence that those experiments resulted in a control composition that worked for its intended purpose. The evidence that R&D's control composition worked, and that Dr. Johnson appreciated the fact that it worked was thin at best. Dr. Johnson's testimony was supported by an almost total lack of contemporaneous data with respect to the success or failure of the trials. The evidence of any such success was highly equivocal and related mainly to the notion of stability over time, rather than to the absence of interference between the five white-cell differentials and the reticulocytes and the proper positioning of cells. Any argument that scattergrams were not necessary to ascertain proper positioning or that cells' positions could be determined with reference to the raw data is undercut by 1) the overall absence of such data; and 2) the lack of definitive evidence with respect to the components that originally went into the samples for the Johnson controls. Moreover, Dr. Johnson's

testimony that he had sufficiently reduced his claimed conception to practice was largely uncorroborated. The jury could reasonably have rejected R&D's evidence of corroboration.

Also, there was considerable evidence that undermined R&D's claim that it was the first inventor. Most notably, R&D did not proceed with further testing or experimentation at the time. It did not release a commercial product until much later. Second, Johnson's statements in memos and reports to management at the time did not indicate that Dr. Johnson felt at the time that he had successfully developed a control that worked for its intended purpose. R&D's evidence shows that the integrated control lacked stability and had numerous problems.

In contrast, Streck's scientific evidence is heavily documented and lends credence to the testimony of Dr. Ryan and others that Streck was the first to invent the control composition. Each of the Streck scientists performing the experiments reported their findings to their supervisors, Dr. Ryan and/or Mr. Scholl, and all believed that the integrated control compositions that they tested had worked for their intended purpose. Accordingly, the court finds that R&D's motion for new trial on the issue of prior inventorship should be denied.

The court further finds that Streck presented undisputed evidence that its invention was properly enabled. Dr. Ryan testified that it was clear in the prior art that animal cells could substitute for reticulocytes in a control and that he had in fact developed controls using animal cells. His reasons for abandoning animal cells as reticulocyte substitutes had to do with the practical difficulties and substantial costs of maintaining a supply of animals, rather than any perceived "unworkability" of the cells to function as a control for reticulocytes. R&D did not show that it would require any "undue experimentation" by a

person skilled in the art to create a control composition with other reticulocyte analogs than those described in the patent.

With respect to the joint and several liability issue, the evidence shows that Techne is a holding company for R&D, it has the same employees, the same address, and the same officers and directors. The companies are essentially one and the same entity. The court finds R&D and Techne are jointly and severally liable for infringement. Accordingly,

IT IS ORDERED that R&D's renewed motion for judgment as a matter of law and motion for a new trial (Filing No. 326) is denied.

DATED this 30th day of September, 2010.

BY THE COURT:

s/ Joseph F. Bataillon
Chief United States District Judge

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